



CERTIFICATE OF ANALYSIS

STP CCX Cal Cartridge 2 w/Creat
Lot Number 16319013

Ref Number 36252

Exp Date 2017-11-03

Date of Manufacture 2016-11-03

UDI# (01)00385480362528(11)161103(17)171103(10)16319013

Cal A L/N	16308020		Cal B L/N	16308020		Cal C L/N	16308020	
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
pH @ 37C	7.351-7.357	Pass	pH @ 37C	6.822-6.828	Pass	Na mmol/L	139.0-141.0	Pass
Lac mmol/L	13.5-16.5	Pass	Na mmol/L	69.5-70.5	Pass	K mmol/L	3.97-4.03	Pass
			K mmol/L	9.9-10.1	Pass	Cl mmol/L	118.0-120.0	Pass
			Cl mmol/L	39.7-40.3	Pass	BUN mg/dl	9.9-10.1	Pass
			Ca mmol/L	1.97-2.03	Pass	Glu mg/dl	78.8-81.2	Pass
			Mg mmol/L	1.48-1.52	Pass	Lac mmol/L	1.8-2.2	Pass
						Ca mmol/L	0.98-1.02	Pass
						Mg mmol/L	0.49-0.51	Pass
						Creat mg/dl	0.98-1.02	Pass
						HCO3 mmol/L	18.34-19.08	Pass
Cal D L/N	16308020		Flush L/N	16308020		Reference L/N	16308020	
	Spec	Pass/Fail		Spec	Result		Spec	Pass/Fail
BUN mg/dl	49.4-50.6	Pass	Aqueous Salt	N/A	Present	KCl mol/L	1.8-2.2	Pass
Glu mg/dl	197-203	Pass	Solution					
Lac mmol/L	5.5-6.5	Pass						
Creat mg/dl	9.8-10.2	Pass						
HCO3 mmol/L	36.68-38.18	Pass						

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Approval

QC Supervisor
Title

4/10/2017
Date